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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/590,543

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EXAMINER

MI, QIUWEN

ART UNIT

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1655

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/590,543	Applicant(s) GIULIANI ET AL.	
	Examiner Qiuwen Mi	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 3,4 and 9-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Election/Restrictions**

Applicant's election with traverse of phenylpropanoids, *Ajuga reptans*, and topical in the reply filed on 11/15/07 is acknowledged. The traversal is on the ground(s) that the general inventive concept of the present invention is the regulation of the trophism of the follicles and/or skin production of sebum which is common to the species groups set forth in the office action. This is not found persuasive because the species groups are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The requirement is still deemed proper and is therefore made FINAL.

Claims 3, 4, and 9-13 are withdrawn from further consideration as being drawn to nonelected inventions.

### **Claims Pending**

Claims 1-13 are pending. Claims 3, 4, and 9-13 are withdrawn as they are directed toward a non-elected invention groups or species. Claims 1, 2, and 5-8 are examined on the merits.

### **Claim Objections**

Claims 1, and 6-8 are objected to because of the following informalities: Claims 1, and 6-8 recite "*Boehmeria nippononivea*", and correct spelling of the plant name is "*Boehmeria nippononivea*". Appropriate correction is required.

### **Specification/Abstract Objections**

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

In the instant case, Applicant is required to delete "The present invention relates to" on line 1 of the Abstract to be more clear and concise. The first letter of "a" in line 1 should be capitalized after the deletion.

### **Claim Rejections –35 USC § 112, 1st**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Androgenetic alopecia and/or telogenic defluvium, acne and/or seborrhea, hypertrichosis and/or hirsutism cannot be prevented. There is no evidence that one would not ever get androgenetic alopecia and/or telogenic defluvium, acne and/or seborrhea, hypertrichosis and/or hirsutism by applying the claimed composition. Unless Applicant can show on the record that androgenetic alopecia and/or telogenic defluvium, acne and/or seborrhea, hypertrichosis and/or hirsutism would be completely prevented in every instance, Applicant is requested to cancel the word "prevention".

**Claim Rejections –35 USC § 112, 2<sup>nd</sup>**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-8 provide for the use of "an extract of *Boehmeria nippononivea*...", but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

### **Claim Rejections –35 USC § 101**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6-8 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### **Claim Rejections –35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Shimizu et al (Steroid 5-alpha-reductase inhibitory activity and hair regrowth effects of an extract from *Boehmeria nipononivea*, Biosci. Biotechnol. Biochem., 64 (4), 875-877, 2000) and Lu et al (US 2003/0091659).

Shimizu et al teach that the acetone extract of *Boehmeria nipononivea* showed hair regrowth promotion effects on mice (topical) (see Abstract). Shimizu et al also teach that *Boehmeria nipononivea* has potent 5-alpha-reductase inhibitory activity.

Shimizu et al do not teach the incorporation of *Ajuga reptans* into the composition.

Lu et al teach a topical composition having undifferentiated plant seed cells including *Ajuga reptans* (inherently containing phenylpropanoids that act at the level of the epithelial structures) etc [0027, 0029], and the method for using the same (see Title). Lu et al teach that the active may be useful in preventing, arresting, ameliorating, diminishing or treating medical and/or cosmetic conditions of the skin, nail, lips or hair. Such conditions commonly include, but not limited to, hair loss, etc [0029].

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ...[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted).

In the instant case, all of the above-listed ingredients were known for hair regrowth or treating hair loss. Thus, one of ordinary skill in the art would have had a reasonable expectation that the combination of these compounds would have been additively beneficial in for hair regrowth or treating hair loss.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known for hair regrowth or treating hair loss. This rejection is based on

the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, In re Sussman, 1943 C.D. 518.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the amounts of each constituent as in the claims, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to combine the inventions of Shimizu et al and Lu et al since both of them teach compositions for hair regrowth or treating hair loss individually in the art. Since all the compositions yielded beneficial results in treating hair loss, one of ordinary skill in the art would have been motivated to make the modifications.



“the use of...” claims are treated as composition claims, see the 101, and 112, 2<sup>nd</sup> rejections above for details.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

The intended use of the composition in claim 1 was analyzed for patentable weight. It is deemed that the preamble ‘breathes life’ into the claims in that it is deemed that the prior art product must not be precluded for use as regulating the trophism of follicles and/or the skin production of sebum, or inhibiting the 5-alpha-reductase etc. It is deemed that the composition disclosed by the cited references is not precluded for carrying out the intended function of the claims.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

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### **Conclusion**


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Qiuwen Mi



MICHAEL MELLER  
PRIMARY EXAMINER